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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,241

09/25/2003

Mark Korsten

6915-66816

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24197 7590 02/27/2007  
KLARQUIST SPARKMAN, LLP  
121 SW SALMON STREET  
SUITE 1600  
PORTLAND, OR 97204

EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/672,241

Applicant(s)

KORSTEN, MARK

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/29/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Applicants election without traverse of claims 1-26, drawn to a method of bowel care, comprising chronically administering a therapeutically effective amount of a drug combination comprising an acetylcholinesterase inhibitor and an anti-cholinergic agent to a subject having a chronic intestinal pseudo-obstruction, and cancellation of non elected invention of claims 27-31 drawn to non-elected invention is acknowledged.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponec et al. (1999) of record in view of Vavilala et al. (1999).

Ponec et al. teach that neostigmine is useful for the treatment of acute colonic pseudo-obstruction. (title). Ponec et al. teach that in patients with acute colonic pseudo-obstruction who have not had a response to conservative therapy, treatment with neostigmine rapidly decompresses the colon. (page 137, left-hand column under Conclusions). Ponec et al. teach that side effect of neostigmine of symptomatic bradycardia developed in two patients and was treated with atropine. (page 137 under Results). Ponec et al. teach that patients with acute colonic pseudo-obstruction received 2.0 mg of neostigmine intravenously over a period of three to five minutes. This amount overlap with Applicant's amount set forth in claims 7-9 and 23. Ponec et al. teach that acute colonic pseudo-obstruction may develop after surgery or severe illness and that colonoscopic decompression is needed to prevent ischemia and perforation of the bowel. (abstract).

Ponec et al. lack glycopyrrolate for the treatment of pseudo-obstruction and various medical conditions resulted in pseudo-obstruction, other routes of administration, and dosing frequencies.

Vavilala et al. teach that neostigmine for acute colonic pseudo-obstruction rapidly decompresses the colon in patients with acute colonic pseudo-obstruction but causes bradycardia. Vavilala et al. teach that the bradycardia is a well-recognized and important complication of neostigmine therapy. Vavilala et al. teach that the use of neostigmine is always accompanied by administration of an antimuscarinic

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anticholinergic agent such as atropine or glycopyrrolate to reverse this effect.

(abstract).

It would have been obvious to one ordinary skill in the art at time the invention was made to combine neostigmine and glycopyrrolate in bowel care or to combine to treat pseudo-obstruction in a patient because neostigmine is useful for the treatment of pseudo-obstruction by rapidly decompressing the colon and because glycopyrrolate is useful for preventing the development of adverse effect of neostigmine such as bradycardia. One would have been motivated to combine neostigmine and glycopyrrolate in a single component in order to achieve rapid decompression of colon in patients suffering from pseudo-obstruction without the complications of bradycardia, well recognized and important adverse effect of neostigmine. One would have been motivated to make such a modification in order to prevent well-recognized and important complication well-recognized in neostigmine therapy. Moreover, it is well known by Vavilala et al. that neostigmine is always accompanied by the administration of atropine or glycopyrrolate to reverse the adverse effect result from neostigmine. The amounts of active agent (glycopyrrolate) to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration and cause of resulted condition are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. One of ordinary skill in the art would optimize the dosage of glycopyrrolate taught by Vavilala in the obvious combination in order to customize the dosage needed based on the patients physical and medical profile. Furthermore, there is an expectation of successfully treating

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pseudo-obstruction in a patient regardless of the cause because the neostigmine comprising therapy is effective for treating such condition as taught by Ponec et al.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'Jennifer Kim', is positioned above the printed name.

Jennifer Kim  
Patent Examiner  
Art Unit 1617

Jmk  
February 19, 2007